K052334

510(k) SUMMARY

SEP - 2 2005

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: August 23, 2005

TRADE OR PROPRIETARY NAME: **Model G-131, CAVITRON® RF Ultrasonic Scaler System with Sterimate Handpiece**

CLASSIFICATION NAME: **Ultrasonic scaler 872.4850**

PREDICATE DEVICES: **DENTSPLY Cavitron SPS Scaler System, Model G-119 (K970123)**

DEVICE DESCRIPTION: The Modified Device, the Model G131 consists of the Cavitron RF Ultrasonic Scaler, Sterimate handpiece, and the applicable model families of Cavitron 30K Ultrasonic Inserts.

The Model G-131 Cavitron RF Ultrasonic Scaler with Sterimate handpiece is a 30K ultrasonic dental device that provides an electrical signal to the detachable, sterilizable handpiece. The electronic signal develops a fluctuating electromagnetic field, pulsed at 30 kilohertz (kHz) through the length of the handpiece. When a magnetostrictive insert, designed to resonate near 30kHz is inserted into the handpiece it will vibrate at the designed resonance which in turn excites the working tip, causing it to stroke in reciprocal motion. The system operates over a frequency range of 28.5 to 31.5 kHz. The input voltage of the Scaler is 100 – 240 VAC, 50 to 60 Hz

INTENDED USE: Used for ultrasonic procedures: 1) All general supra and subgingival scaling applications; Periodontal debridement for all types of periodontal diseases; and 3) Endodontic procedures

TECHNOLOGICAL CHARACTERISTICS: The Cavitron RF magnetostrictive ultrasonic scaling system is a device intended for counter top use to mechanically debride (remove tartar) from human dentition. The scaling system drives an ultrasonic insert designed with a resonate frequency near 30kHz to produce mechanical vibration at the distal end of the insert tip. The system provides a means for control of power (tip stroke) and lavage flow rates. The system is activated by a footswitch which communicates through a RF link or through an auxillary hardwired cable. The footswitch has two positions which activates a water solenoid or ultrasonic energy to the handpiece.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2005

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
Susquehanna Commerce Center West
221 West Philadelphia Street
York, Pennsylvania 17404

Re: K052334
Trade/Device Name: Cavitron RF Ultrasonic Scaler System with Sterimate Handpiece
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: II
Product Code: ELC
Dated: August 23, 2005
Received: August 26, 2005

Dear Ms. Lewis:

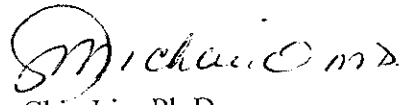
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052334

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): _____

Device Name: **Model G-131, CAVITRON® RF ULTRASONIS SCALER SYSTEM WITH STERIMATE HANDPIECE**

Indications for Use:

Used for ultrasonic procedures:

- All general supra and subgingival scaling applications
- Periodontal debridement for all types of periodontal diseases
- Endodontic procedures

Prescription Use _ X __ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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